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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/597,624 | 08/01/2006 | Stanley George Bonney | PB60733-A USW | 3953 |
| 23347 | 7590 | 08/07/2009 | | |
| GLAXOSMITHKLINE CORPORATE INTELLECTUAL PROPERTY, MAI B482 FIVE MOORE DR., PO BOX 13398 RESEARCH TRIANGLE PARK, NC 27709-3398 | | | EXAMINER CAMPBELL, VICTORIA P | |
| | | | ART UNIT 3763 | PAPER NUMBER |
| | | | NOTIFICATION DATE 08/07/2009 | DELIVERY MODE ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | | |
|------------------------------|---|--------------------------------------|--|
| Office Action Summary | Application No. 10/597,624 | Applicant(s) BONNEY ET AL. | |
| | Examiner VICTORIA P. CAMPBELL | Art Unit 3763 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24,36-69,85 and 92 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12,14-16,18,19,21-24,36-45,48,49,53,54,56-65,67-69,85 and 92 is/are rejected.
- 7) ☒ Claim(s) 13,17,20,46,47,50-52,55 and 66 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/1/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is the initial Office Action based on the 10/597624 application filed August 1, 2006.

Claims 1-24, 36-69, 85, and 92 as presented in the preliminary amendment are currently pending and considered below.

Specification

1. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

2. Claim 56 recites the limitation "the container unit" in line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim.

3. Claim 85 is objected to because of the following informalities: the claim does not end in a period ---. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 1-12, 14-16, 18, 19, 21-24, 36-45, 48, 49, 53, 54, 56-65, 67-69, 85, and 92 are rejected under 35 U.S.C. 102(b) as being anticipated by USPN 5,085,351 to Martin.

Regarding the above claims, Martin discloses a fluid dispenser having a storage chamber (20, 22) for storing a fluid product; a dispensing outlet (46); a metering chamber (62a, 62b, 62c, and portion enclosed by 34, 37, and 52) adapted to provide the metered volume of the fluid product for dispensing through the dispensing outlet by movement of the metering chamber between a contracted state (Fig. 2) and an expanded state (Fig. 1), movement between these states placing the metering and storage chambers in fluid communication (Fig. 1) to enable the metering chamber to receive from the storage chamber an excess volume (Fig. 1) comprising the metered volume (amount in chamber 62a, b, or c) and a surplus volume; and a bleed arrangement (72) adapted to bleed the surplus volume of the fluid product from the metering chamber wherein the metering chamber is defined by a boundary wall having a first section (24, 30, 50, 52, and 37) movably mounted in the dispenser (16) to move the metering chamber between the states and that the first section and the storage chamber are provided by a container unit (including 12).

Further, Martin discloses at least one transfer port (72) is formed in the first section through which the fluid product is transferable from the storage chamber to the metering chamber when the metering chamber moves to the expanded state, that the transfer port is selectively opened and closed when the metering chamber moves between states, and that the transfer port is closed when the metering chamber is at an

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intermediate state (which is defined by the examiner as the state in which the transfer port is closed, but the flexible member (24) has not yet been pushed into one of the chamber (62)) between its expanded and contracted states. Martin further discloses that the metering chamber has a volume substantially corresponding to the metered volume in the intermediate state, and that the transfer port is closed between the intermediate and contracted states and open between the intermediate and expanded states.

Additionally, Martin discloses that the boundary wall has a second section (42, 60) and the metering chamber is movable between states by movement of the first section relative to the second, that the second section is stationary in the dispenser (see Figs. 1 and 2), and that the second section is adapted in use to selectively open and close the transfer port (70). Martin also discloses an outlet port (56) disposed on the second section and that the container unit is adapted to operate as a pump mechanism for filling and emptying of the metering chamber, that the movement of the metering chamber pumps the fluid product out of the metering chamber, and that the metering chamber is repeatedly movable between states for repeated use.

Martin also discloses an outlet valve mechanism (50, 52, 56) adapted to keep the dispensing outlet closed until after bleeding is complete, only allows the metered volume to escape the outlet, and is configured to close the outlet except when the metering chamber moves to its contracted state after the bleeding process.

Martin further discloses that the dispensing outlet is a nozzle (16) which is a mouthpiece or nasal nozzle (Col. 1, lines 18-19). Furthermore, Martin discloses that the

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bleeding arrangement bleeds the surplus volume from the metering chamber to the storage chamber, through the transfer port.

Martin continues to disclose that the container unit is mounted for translational movement along an axis which contains the storage chamber, metering chamber, outlet port, and dispensing outlet, wherein the outlet port and dispensing outlet are at opposed ends of an axial channel of the dispenser (see Figs. 1 and 2).

Martin also discloses that the first section of the metering chamber is sealingly, slidably mounted on the second section (50 and 52 slide around 42), that the first section of the metering chamber presents a movable end wall (wall comprising lip 72), which has a generally U-shape (see Figs.), and that the second section presents an end wall of the metering chamber which has a generally U-shape structure (see Figs.).

Martin also discloses that the first section is formed by a female depression in an outer surface of the container unit (34), that the second section is formed as a male projection inserted into the female depression (60, 68), that the depression extends into the storage chamber, that the storage chamber surrounds the depression, that at least a portion of the storage chamber surrounds the metering chamber, and that at least a portion of the storage chamber is concentrically arranged with the metering chamber (see Figs. 1 and 2). Further, Martin discloses that the metering chamber has substantially zero volume when in its contracted state, that the first and second sections abut in a contracted state, and that the first and second sections are of complementary shape which next in the contracted state.

Martin also discloses that the device is hand-held having a manually-operable actuating mechanism (16) for actuating movement wherein the actuating mechanism has a manually-engageable actuator member (16) operatively coupled to the container unit to move the container unit such that the metering chamber completes a cycle between states (Figs. 1 and 2).

Finally, Martin discloses that bleeding of the product occurs as the metering chamber is moved from the expanded to contracted state and that the dispensing outlet is a dispensing outlet of the unit through which the metered volume is delivered to the environment (Figs. 1 and 2).

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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7. Claims 1-24, 36-69, 85, and 92 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24, 36-69, 85, and 92 of copending Application No. 10/597678, claims 1-22, 34-69, 83, and 90 of copending Application No. 10/597683, claims 1-37 of copending Application No. 10/597692, claims 1-46 of copending Application No. 10/597703, and claims 1-25, 37-71, 85, and 92 of copending Application No. 10/597690. Although the conflicting claims are not identical, they are not patentably distinct from each other because all of the above applications claim in some combination a fluid delivery device having a storage and a metering chamber wherein the metering chamber is comprised of two members in slideable, sealing engagement for measuring out an excess volume of product, bleeding the surplus volume of product, and delivery of the metered dose through an outlet.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

8. Claims 13, 17, 20, 46, 47, 50-52, 55, and 66 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victoria P Campbell
Examiner, AU 3763

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/Nicholas D Lucchesi/

Supervisory Patent Examiner, Art Unit 3763